

K024225

Summary of Safety and Effectiveness  
Liquichek™ Anti-nDNA Control, Positive

JAN 15 2003

1.0 **Submitter**

Bio-Rad Laboratories  
9500 Jeronimo Road,  
Irvine, California 92618-2017  
Telephone: (949) 598-1200  
Fax: (949) 598-1555

**Contact Person**

Yvette Lloyd  
Senior Regulatory Affairs Specialist  
Telephone: (949) 598-1465

**Date of Summary Preparation**

December 20, 2002

2.0 **Device Identification**

Product Trade Name: Liquichek™ Anti-nDNA Control, Positive  
  
Common Name: Antinuclear Antibody, Indirect Immunofluorescent,  
Antigen, Control  
  
Classifications: Class II  
Product Code: 82DHN  
Regulation Number: 21 CFR 866.5100

3.0 **Device to Which Substantial Equivalence is Claimed**

Kallestad™ Autoantibody Positive Control  
Bio-Rad Laboratories  
  
510 (k) Number: K780899A

4.0 **Description of Device**

This product is prepared from human serum with added preservatives. The control is provided in liquid form for convenience.

## 5.0 **Statement of Intended Use**

The Liquichek™ Anti-nDNA Control, Positive is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of nDNA autoantibodies.

## 6.0 **Comparison of the new device with the Predicate Device**

This control is substantially equivalent to the following quality control material for autoimmune analysis that is currently in the market:

Kallestad™ Autoantibody Positive Control  
Bio-Rad Laboratories

510 (k) Number: K780899A

**Table 1.** Similarities and Differences between new and predicate device.

<b>Characteristics</b>	<b>Liquichek™ Anti-nDNA Control, Positive (New Device)</b>	<b>Kallestad™ Autoantibody Positive Control (Predicate Device)</b>
<b>Similarities</b>		
<b>Intended Use</b>	The Liquichek™ Anti-nDNA Control, Positive is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of nDNA autoantibodies.	The Autoantibody Positive Control is a replacement reagent in the Kallestad Fluorescent Autoantibody test with mouse kidney, mouse stomach/kidney, Hep-2 cell line, or Crithidia luciliae substrates.
<b>Matrix</b>	Human Serum	Human Serum
<b>Storage (Unopened)</b>	2°C to 8°C until expiration date	2°C to 8°C until expiration date
<b>Differences</b>		
<b>Stability (Opened)</b>	Once opened the analyte will be stable for 60 days.	Aliquots of the reconstituted solution are stable at 2-8°C for 6 weeks and at -20°C for 4 months.
<b>Form</b>	Liquid	Lyophilized
<b>Analyte</b>	Anti-nDNA	ANA: Centromere Pattern, SSA, SSB, Scl-70, Sm, RNP, Spindle Pattern, Nucleolar Pattern AMA ASMA APCA Anti-nDNA

## 7.0 **Summary of Performance Data**

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Anti-nDNA Control, Positive. Product claims are as follows:

7.1 Once the control is opened the analyte will be stable for 60 days when stored tightly capped at 2 to 8°C.

7.2 The control is stable for 2 years when stored unopened at 2 - 8°C.

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 15 2003

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Yvette Lloyd  
Senior Regulatory Affairs Specialist  
Bio-Rad Laboratories, QSD  
9500 Jeronimo Road  
Irvine, California 92618-2017

Re: k024225  
Trade/Device Name: Liquichek™ Anti-nDNA Control, Positive  
Regulation Number: 21 CFR § 866.5100  
Regulation Name: Antinuclear Antibody (Indirect)/Immunofluorescent, Antigen, Control  
Regulatory Class: II  
Product Code: DHN  
Dated: December 20, 2002  
Received: December 23, 2002

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

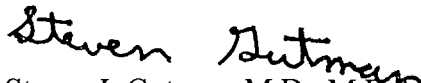
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

  
Steven I. Gutman, M.D., M.B.A.

Director  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

510 (k) Number (if known): K024225

Device Name: **Liquichek™ Anti-nDNA Control, Positive**

Indications for Use:

**The Liquichek™ Anti-nDNA Control, Positive is intended for use as an unassayed quality control to monitor indirect immunofluorescent testing for the detection of nDNA autoantibodies.**

(PLEASE DO NOT WRITE BELOW THE LINE-CONINUE ON ANOTHER PAGE IF NEEDED)

---

*Concurrence of CDRH, Office of Device Evaluation (ODE)*

Prescription use ✓ or Over-the Counter use \_\_\_\_\_

*J. Bantista*  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K024225